

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION**

RAVGEN, INC.,

Plaintiff,

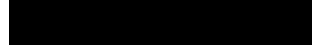
v.

NATERA, INC. AND NSTX, INC.,

Defendants.

**Civil Action No. 1:20-cv-00692-LY**

**JURY TRIAL DEMANDED**



**DEFENDANTS NATERA, INC. AND NSTX, INC.'S MOTION FOR  
LEAVE TO AMEND THEIR ANSWER AND DEFENSES**

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Though this case is stayed, the Court asked the parties to submit a Joint Status Report with their respective proposals for further proceedings in this case. Dkt. 281. As indicated in that Report, Natera seeks to amend its Answer to add a release/license defense. *Id.* at 13. In view of the fact that courts consider the motion's timing in deciding it, Natera respectfully submits its motion to amend now.

## **I. INTRODUCTION**

More than two months after the deadline to amend pleadings, and only two weeks before the close of fact discovery, Ravgen produced a patent license agreement between itself and a Natera supplier, Thermo Fisher (the "Agreement" and "TF," respectively), that significantly limits—if not entirely eliminates—Ravgen's damages claim against Natera. The implications of this Agreement are so sweeping that Judge Klausner in the Central District of California interpreted it to release another Ravgen defendant similarly situated to Natera. Were Judge Klausner's interpretation applied here, it would also release Natera from at least a very substantial portion of Ravgen's damages claim in this case. Natera respectfully moves to amend its answer to add a release/license affirmative defense based on this Agreement. This proposed amendment is warranted under Fed. R. Civ. P. 15(a) and 16 for at least three reasons:

**First**, this release/license defense is highly relevant to the proper resolution of this case. The Agreement (1) irrevocably released customers and end-users of TF products from all Ravgen patent infringement claims prior to the Agreement's June 23, 2021 effective date; and (2) granted a going-forward license that extends to TF customers. Natera is and has been a TF customer for the relevant period and, every time the Natera tests at issue in this case have been performed, Natera has used TF products to do so. As a result, under the plain terms of the Agreement, the release and license apply to Natera. Judge Klausner interpreted the terms in exactly this way when granting summary judgment that the Agreement released another TF customer—Quest—from all

damages prior to the effective date because Quest—*just like Natera*—used TF products in its prenatal tests. Were it applied here, Judge Klausner’s ruling would eliminate at least \$216 million from Ravgen’s damages claim.

*Second*, as a practical matter, Natera did not have a reasonable opportunity to raise this defense or amend its pleadings earlier. Ravgen produced the Agreement on July 7, 2021—two months *after* the deadline to amend, and only two weeks before the close of fact discovery—and the case was subsequently stayed. So Natera could not have raised this defense before the deadline to amend and did not have a realistic opportunity to raise it in the original fact discovery period. Moreover, there have been significant developments since the case was stayed that are relevant to the defense. Judge Klausner interpreted the Agreement to release TF customers such as Natera after the case was stayed. Then, Ravgen tried to amend the Agreement to undo those rights. But the rights conferred are “irrevocable” and Ravgen’s attempt to remove them from the Agreement only underscores that the Agreement in fact confers such rights. Because both of those events occurred after the stay, Natera could not have addressed them earlier.

*Finally*, adding this defense would not prejudice Ravgen, but excluding it would significantly prejudice Natera. Ravgen itself just proposed re-opening and supplementing the record based on developments during the stay. *See* Dkt. 281 at 5. And on this issue, Ravgen is uniquely prepared—it already has the relevant facts regarding the release/license; it negotiated and executed the Agreement that gives rise to the defense; and it already litigated (and lost) the release issue in the Quest case. The only possible prejudice would be to Natera, if Ravgen were permitted to seek hundreds of millions of dollars in damages on sales it has already released/licensed.<sup>1</sup>

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<sup>1</sup> During the parties’ meet-and-confer, Ravgen suggested that the Court foreclosed amendment of pleadings during the February 28, 2023 status conference. That is incorrect. To the contrary, Natera indicated that it wished to amend its Answer to add a release/license defense—citing,

## II. FACTUAL BACKGROUND

### A. Ravgen Entered A Release/License Agreement With A Natera Supplier.

Ravgen entered the Agreement with TF on June 23, 2021. Under the Agreement, Ravgen granted TF *and TF’s customers, purchasers, and end users*, such as Natera, certain rights to Ravgen’s patent portfolio. Specifically, Ravgen agreed to irrevocably release infringement claims against TF’s customers, purchasers, and end-users arising prior to the Agreement, and to extend going-forward license rights to those customers:

- The Release: The Agreement defines “[TF] Released Parties” as “past, current and future...end use and non-end use *customers, purchasers* and/or *end users of any Covered Products*, but solely to the extent of their import, purchase, possession, use or resale of Covered Products directly or indirectly from [TF] or its Affiliates.”<sup>2</sup> Ex. 1, Agreement, § 1.10. The “Covered Products” include “*any* [TF] or [TF] Affiliate product.” *Id.*, §1.2. And the “Ravgen Licensed Patents” include the two patents—the ’277 and ’720 patents—asserted here. *Id.*, §1.6. Under Section 2.2 of the Agreement, “*Ravgen...irrevocably, unconditionally, absolutely and forever, releases*, acquits and discharges the [TF] Released Parties from any claim...for *any alleged past infringement* of the *Ravgen Licensed Patents* prior to the Effective Date [June 23, 2021] of this Agreement, or for any acts that might be deemed infringement of the Ravgen Licensed Patents.” *Id.*, § 2.2.

- The License: Under Section 2.1 of the Agreement, “Ravgen...grants [TF]...a perpetual, irrevocable, fully paid up, worldwide license under the Ravgen Licensed Patents,

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among other evidence, Judge Klausner’s ruling—and, at the conclusion of the hearing, the Court then specifically requested a copy of Judge Klausner’s order. Feb. 28, 2023 Hr’g Tr. at 15:3-16:5, 33:14-19 (The Court: “I want you to provide me with a copy of Judge Klausner’s ruling that is no longer in effect, because *if that comes up again, I want to be able to read it and hear what you’re arguing about it*. So I want a copy of that, too.” (emphasis added)).

<sup>2</sup> Emphases added, unless otherwise noted.

to...sell...Covered Products, and to practice...any method, process and/or procedure claimed in the Ravgen Licensed Patents in connection with the manufacture, use, or sale of Covered Products.” *Id.*, § 2.1. The Agreement then extends these rights to TF customers: “The foregoing *license shall also include the right to extend to [TF]’s...customers, and users the rights to (i) use the Covered Products, including to perform services.*” *Id.*

**B. The Release And License Apply To Natera.**

Natera is a TF customer, purchaser, and end-user. Ex. A, ¶109. Every time the Natera tests at issue have been performed, Natera has used TF equipment and consumables to do so. *Id.* The release and license thus apply to Natera. *Id.* In fact, Judge Klausner granted summary judgment that the Agreement released defendant and TF customer Quest from Ravgen’s claims of past damages because Quest, like Natera, used TF products in performing its tests:

***[T]he Court finds that Quest qualifies as a Released Party under the [Agreement] and is released for any alleged past infringement of the Ravgen Licensed Patents prior to the Effective Date of this Agreement, or for any acts that might be deemed infringement of the Ravgen Licensed Patents that occurred prior to June 23, 2021.***

Ex. 2, *Ravgen, Inc. v. Quest Diagnostics Incorporated*, No. 21-9011-RGK-GJS (C.D. Cal. Sept. 26, 2022), Dkt. 449 at 7 (“*Quest*”) (punctuation omitted). In reaching that conclusion, the Court specifically rejected Ravgen’s “strained interpretation” of the Agreement whereby—according to Ravgen—the release applied only to the use of TF products “alone.” *Id.* at 6. A week later, Ravgen settled that case and dropped its claims on the condition that Judge Klausner vacate that summary judgment decision; the Court agreed to Ravgen’s request but never retracted its reasoning. Ex. 3, *Ravgen, Inc. v. Quest Diagnostics Incorporated*, No. 21-9011-RGK-GJS (C.D. Cal. Oct. 7, 2022), Dkt. 492 at 1-2. Applied here, the release alone would eliminate \$216 million from Ravgen’s damages claim. Ex. 4, Meyer Rpt., ¶19 (Ravgen damages expert’s report summarizing royalty opinion, i.e., \$216,282,825 in damages, predating the Agreement’s June 2021 effective date). The

going-forward license could potentially eliminate all of Ravgen’s claims against Natera, making this issue case dispositive. Ex. 1, Agreement § 2.

Moreover, in other Ravgen cases, another court has allowed TF customers to plead this same defense. Just last week, Magistrate Judge Hall of the District of Delaware granted defendants Biora, Roche, Foundation Medicine, and Myriad’s opposed motions to amend their Answers to add defenses based on the Agreement. Ex. 5, Biora Mot. to Amend at 2-3; Ex. 6, May 29, 2023 Hr’g Tr. at 63:21-65:3. In reaching that conclusion, the court specifically rejected Ravgen’s argument that the proposed amendments would be “futile.” *Id.*

**C. Ravgen’s Subsequent Attempts To Amend The Agreement.**

After Judge Klausner’s ruling, [REDACTED]

[REDACTED] But the rights granted under the Agreement are “irrevocabl[e],” and thus could not be eliminated without consent. *Infra* at 10. [REDACTED]

[REDACTED] Ravgen’s attempt is thus only further evidence that, as Judge Klausner found, the Agreement conveyed such rights.

**D. The Agreement Was Produced After The Deadline To Amend And Only Two Weeks Before The Close Of Fact Discovery.**

The Agreement was entered on June 23, 2021 and produced to Natera on July 7, 2021, two months after the deadline to amend pleadings and only two weeks before the close of the original fact discovery period. Dkt. 66 at 3; Ex. 7, Ravgen Production Letter; Dkt. 91; Sept. 13, 2021 Margin Order. The case was reassigned to this Court in November 2021, and stayed thereafter. Nov. 22, 2021 Margin Order; Dkt. 247. Judge Klausner’s summary judgment decision in *Quest* and Ravgen’s attempts to amend the Agreement occurred after the case was stayed.



The case currently remains stayed. At the Court’s request, the parties submitted competing proposed schedules on March 22, 2023, pursuant to which fact and expert discovery should be reopened. Dkt. 281. A Scheduling Order has not yet entered, and there is no trial scheduled.

### **III. ARGUMENT**

A party may amend its pleadings after the scheduling order deadline to do so where it can show good cause under Rule 16(b). *Sw. Bell Tel. v. City of El Paso*, 346 F.3d 541, 546 (5th Cir. 2003). After showing good cause to excuse the scheduling order deadline, “the more liberal standard of Rule 15(a)” applies, whereby “leave shall be freely given when justice so requires.” *S&W Enterprises v. SouthTrust Bank*, 315 F.3d 533, 535-36 (5th Cir. 2003). Here, good cause exists to amend to add Natera’s contract defense, and Rule 15’s liberal standard is met.

#### **A. Good Cause Exists To Amend Under Rule 16(b).**

In deciding whether there is good cause to amend a pleading under Rule 16(b), courts consider: “(1) the explanation for the failure to timely move for leave to amend; (2) the importance of the amendment; (3) potential prejudice in allowing the amendment; and (4) the availability of a continuance to cure such prejudice.” *Sw. Bell Tel.*, 346 F.3d at 546. Each factor weighs strongly in Natera’s favor.

##### **1. Moving to amend before the scheduling order deadline was impossible as the Agreement was produced two months *after* the deadline.**

Because the Agreement was executed and produced *after* the Scheduling Order’s deadline to amend pleadings, amending the Answer to assert the contract defense before the scheduling order deadline was not possible. *See AT&T Corp. v. Park I-10 Motors*, 2014 WL 12690126, at \*3 (W.D. Tex. Oct. 20, 2014) (newly discovered evidence supporting new claim provided sufficient explanation for defendant’s motion for leave to amend). Moreover, as a practical matter, because the Agreement was not produced until two weeks before the close of fact discovery, Natera did

not have a realistic opportunity to pursue this defense during discovery. And the significant developments that occurred after the stay was entered—including Judge Klausner’s order in *Quest*, and Ravgen’s subsequent attempt to amend the Agreement—could not have been accounted for before either the deadline to amend pleadings or the close of fact discovery.

**2. Natera’s proposed amendment is important to the resolution of the case.**

Natera’s release/license defense is highly relevant to the proper resolution of this case. Ravgen is seeking hundreds of millions of dollars in alleged damages in this case. *Supra* at 4-5. As another court found as a matter of law, however, the Agreement releases TF customers for alleged infringement before June 23, 2021. Ex. 2, *Quest* at 7; *see* Ex. 1, Agreement § 2.2. Applied here, the release alone would eliminate \$216 million from Ravgen’s damages claim. Moreover, if this Court finds that the going-forward license of the Agreement also applies to Natera, that could potentially eliminate most or even all damages and resolve the case. Ex. 1, Agreement § 2.1; *see Crossroads Sys. V. Dot Hill Sys. Corp.*, 48 F. Supp. 3d 984, 989 (W.D. Tex. Sep. 19, 2014) (“[A] license is a valid defense to patent infringement.”); *EMG Tech., LLC v. Vanguard Grp., Inc.*, 2014 WL 12597424, at \*2 (E.D. Tex. Jan. 27, 2014) (good cause to amend pleadings under Rule 16(b) to add affirmative defense of license that could at least partially reduce liability); *SimpleAir, Inc. v. AWS Convergence Techs.*, 2012 WL 12978325, at \*3 (E.D. Tex. Jan. 31, 2012) (same). Ravgen should not be permitted to seek hundreds of millions of dollars of damages on sales that it has already released and licensed.

**3. Ravgen would suffer no prejudice from Natera’s proposed amendment.**

Natera’s proposed amended pleading would not prejudice Ravgen because Ravgen already has the relevant facts and information, and its own damages expert has relied on the Agreement.

*First*, Ravgen negotiated and executed the Agreement that gives rise to Natera's release/license defense. And Ravgen has already litigated and lost this issue before Judge Klausner. During that proceeding, Ravgen was able to take discovery and be heard on summary judgment in litigation against a similarly situated TF customer. *See Sweetheart Plastics v. Detroit Forming*, 743 F.2d 1039, 1044 (4th Cir. 1984) (no prejudice where non-movant was aware of events from which amendment arose well before motion to amend was filed).

*Second*, Ravgen's own damages expert has put the Agreement at issue here by affirmatively relying on it to advance his damages arguments. *E.g.*, Ex. 4, Meyer Rpt., ¶¶99-103. Having done so, Ravgen should not be permitted to selectively ignore the releases/license clauses in that Agreement that refute Ravgen's overreaching damages theories.

By contrast, Natera would suffer significant prejudice if deprived of the opportunity to be heard on this defense. That would permit Ravgen to seek over two hundred million dollars on sales that it already released, and even more damages it has already licensed. *See LML Patent Corp. v. JPMorgan Chase & Co.*, 2010 WL 11470975, at \*2 (E.D. Tex. Sept. 7, 2010) (allowing amendment after deadline because importance of "proposed amendments outweigh any potential prejudice" to the non-movant despite "the relatively advanced stage" of the case).

#### **4. Natera's proposed amendment would not require a continuance.**

The case remains stayed and there is currently no trial date set. As a result, allowing Natera's amendment would not require a continuance. Moreover, both parties agree that there should be time for the reopening of fact and expert discovery, and submitted their competing scheduling proposals on March 22, 2023. Dkt. 281. This issue can be addressed at the same time the parties address the multiple other developments that occurred during the stay. *See LBS Innovations, LLC v. Aaron Bros., Inc.*, 2012 WL 12897919, at \*3 (E.D. Tex. Nov. 9, 2012) (granting leave to amend where proposed new defenses would not "inevitably delay trial").

Accordingly, there is good cause under Rule 16(b) to allow Natera's amendment to the pleadings to add release/license defenses.

**B. Natera's Motion Should Be Granted Under Rule 15(a)'s Liberal Standard.**

Having established good cause, leave to amend under Rule 15(a) should be "freely" granted. Fed. R. Civ. P. 15(a). In deciding whether to grant a Rule 15(a) motion, courts consider whether: (1) there is undue delay on the part of the moving party; (2) the amendment would unfairly prejudice the opposing party; (3) the amendment is brought in bad faith; or (4) the amendment would be futile. *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004); *see also Sw. Bell Tel.*, 346 F.3d at 546. These factors strongly support allowing the amendment.

**First**, as explained above, Natera could not realistically have raised this defense earlier. *Supra* at 6-7. Thus, there is no undue delay. *See Thomas v. Hughes*, 2018 WL 2996901, at \*4-5 (W.D. Tex. Feb. 22, 2018) (multi-month delay in moving to amend was no reason to deny amendment even though the parties had submitted motions for summary judgment and the amendment would require additional rounds of motion practice). Indeed, Natera brought this motion as soon as the Court made clear that the stay would be lifted.

**Second**, as explained above, there is no prejudice to Ravgen because Ravgen is well aware of all the issues from prior litigation and its own negotiation of the Agreement; instead, it is Natera that would be unfairly prejudiced if deprived of the opportunity to be heard on this defense. *Supra* at 7-8; *see also Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981) (courts may "weigh in the movant's favor any prejudice that will arise from denial of leave to amend").

**Third**, Natera's proposed amendment is brought in good faith based on facts that it has discovered and developed during the stay. Ravgen has not contended otherwise. *See, e.g., Thomas*, 2018 WL 2996901, at \*3 ("Bad faith may bar amendment if the movant was aware of certain facts but failed to plead them in order to gain a tactical advantage.").

*Finally*, Natera’s amendment would not be futile. *See LSREF2 Baron, L.L.C. v. Tauch*, 751 F.3d 394, 398 (5th Cir. 2014) (pleading must merely provide plaintiff “fair notice” of the affirmative advance being advanced); *Slatter v. Triple BS Consulting LLC*, 2021 WL 3598372, at \*2 (W.D. Tex. June 30, 2021) (same). To the contrary, ***two other district courts have already found*** that the defense is not futile. *Supra* at 4-5.

Ravgen has nonetheless argued futility because, according to Ravgen, Natera is not an “intended” beneficiary of the Agreement. But Judge Klausner already ruled to the contrary, finding that the Agreement’s plain language confers rights to TF customers like Natera. Ex. 2, *Quest* at 7; Ex. 1, Agreement, § 1.10. Ravgen has also argued that Natera’s proposed amendment is futile because the release purportedly applied “solely” to the use of TF products “alone.” But Judge Klausner has already rejected that interpretation of the Agreement as “strained.” Ex. 2, *Quest* at 6. And, contrary to Ravgen’s claim, its December 2022 amendment does not render Natera’s amendment “futile,” including because the rights were ***irrevocably*** granted and thus could not be undone without Natera’s consent. *See* Restatement (Second) of Contracts § 311, cmt. a (parties may “create an irrevocable duty” and, when they do, benefits “cannot be varied without the beneficiary’s consent”). To the contrary, Ravgen’s attempt is further evidence that the Agreement, as executed, grants rights to TF customers.

#### IV. CONCLUSION

Ravgen should not be permitted to seek hundreds of millions of dollars in alleged damages for sales it released/licensed under an Agreement it negotiated, litigated, and is relying on in this case. The release/license defense should be added to the case so that the Court can resolve whether Ravgen is entitled to seek any damages at all. Accordingly, Natera respectfully requests that the Court grant its Motion for Leave to Amend Its Answer and Defenses.

Dated: April 7, 2023

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that all counsel of record who are deemed to have consented to electronic service are being served this 7th day of April 2023, with a copy of this document via electronic mail.

/s/ Stephen M. Hash

Stephen M. Hash